

FDAAA Pediatric Study Characteristics through June 27, 2011

Approval Date	Trade Name	Generic or Proper Name (Biologics)	Indication(s)	Ages Studied	Study #	Study Type	Study Design	No Patients	No Centers	No Countries	BPCA (B) PREA (P)
6/15/2011	Zenpep	pancrelipase	Postmarketing study			Study summary pending					P
6/10/2011	Creon	pancrelipase	Postmarketing study			Study summary pending					P
5/18/2011	Humalog	insulin lispro	Use in a continuous insulin infusion pump			Study summary pending					P
5/17/2011	Faslodex Injection	fulvestrant	Use in girls with progressive precocious puberty associated with McCune-Albright Syndrome	< 10 years	1	Pharmacokinetics (substudy of study 2)	Open label/Population Pharmacokinetic	30	0	0	B
5/17/2011	Faslodex Injection	fulvestrant	Use in girls with progressive precocious puberty associated with McCune-Albright Syndrome	< 10 years	2	Efficacy/Safety	Open Label	30	15	6	B
5/6/2011	Plavix	clopidogrel bisulfate	Reduction of the incidence of thrombosis in children with systemic to pulmonary artery shunts for palliation of cyanotic congenital heart disease	neonates - 24 months	1	Pharmacokinetic/Pharmacodynamic	Open Label	92	22	6	B

5/6/2011	Plavix	clopidogrel bisulfate	Reduction of the incidence of thrombosis in children with systemic to pulmonary artery shunts for palliation of cyanotic congenital heart disease	neonates - 24 months	2	Efficacy/Safety	Blind/Placebo	906	134	31	B
4/29/2011	Kytril Injection	granisetron hydrochloride	Prevention of postoperative nausea and vomiting			Study summary pending					P
4/29/2011	Nexium I.V.	esomeprazole sodium	Treatment of Gastroesophageal Reflux Disease (GERD) with erosive esophagitis			Study summary pending					P
4/25/2011	Lamictal XR Extended-Release tablets	lamotrigine	Monotherapy in patients 13			Study summary pending					P
4/15/2011	Actemra	tocilizumab	Treatment of active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients two years of age and older.			Study summary pending					P
3/24/2011	Zyclara Cream, 3.75%	imiquimod	Treatment of external genital and perianal warts/condyloma acuminata	12 - 16 years	1	Efficacy/Safety	Blind/Placebo	3	43	1	P

3/17/2011	Alimta	pemetrexed disodium	Refractory and recurrent solid tumors, including osteosarcoma, Ewing sarcoma/peripheral PNET, rhabdomyosarcoma, and neuroblastoma	>12 months and ≤21 years	1	Dose finding pharmacokinetic study	Open label	33	14	2	B
3/17/2011	Alimta	pemetrexed disodium	Refractory and recurrent solid tumors, including osteosarcoma, Ewing sarcoma/peripheral PNET, rhabdomyosarcoma, and neuroblastoma	>12 months and ≤21 years	2	Efficacy/Safety	Open label	72	multiple - COG	2	B
3/14/2011	Gadavist	gadobutrol	Detect and visualize areas with disrupted blood brain barrier (BBB) and/or abnormal vascularity of the central nervous system	2 - 17 years	1	Safety/Pharmacokinetics/Tolerability	Open Label/Traditional Pharmacokinetic	140	14	4	P
2/25/2011	Intuniv extended-release 1 mg, 2 mg, 3 mg, & 4 mg tablets	guanfacine	Adjunctive treatment with long-acting oral psychostimulants for the treatment of ADHD	6 - 17 years	1	Efficacy/Safety	Blind/Placebo	461	59	1	P
2/3/2011	Makena	hydroxyprogesterone caproate	Reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth			Study summary pending					P

1/30/2011	Menveo	Meningococcal [Groups A, C, Y, and W 135] Oligosaccharide Diphtheria CRM197 Conjugate Vaccine	Active immunization to prevent invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y and W-135			Study summary pending					P
1/18/2011	Natroba Topical Suspension	spinosad	Treatment of head lice infestation in patients 4 years of age and older.		1	Pharmacokinetic/Tolerability	Open Label/Traditional Pharmacokinetic	14	1	1	P
1/19/2011	Natroba Topical Suspension	spinosad	Treatment of head lice infestation in patients 4 years of age and older.		2	Pharmacokinetic/Tolerability	Open Label/Traditional Pharmacokinetic	8	1	1	P
1/20/2011	Natroba Topical Suspension	spinosad	Treatment of head lice infestation in patients 4 years of age and older.		3	Efficacy/Safety	Blind/Parallel Group	31	1	1	P
12/22/2010	Gardasil	Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine	Prevention of anal intraepithelial neoplasia (AIN) grades 1, 2, and 3 caused by HPV types included in the vaccine, and the prevention of anal cancer caused by HPV types 16 and 18	16 – 26 years	1	Safety/Efficacy/Immunogenicity	Randomized/Controlled/ Double-Blind	598	71	18	P
12/21/2010	INOmax for Inhalation	nitric oxide	Prevention of bronchopulmonary dysplasia	2-26 hours	1	Efficacy/Safety	Blind/Placebo	792	35	NA	B
12/21/2010	INOmax for Inhalation	nitric oxide	Prevention of bronchopulmonary dysplasia	7-21 days	2	Efficacy/Safety	Blind/Placebo	584	21	1	B
12/21/2010	INOmax for Inhalation	nitric oxide	Prevention of bronchopulmonary dysplasia	< 48 hours old	3	Efficacy/Safety	Blind/Placebo	793	16	1	B
12/15/2010	Uroxatral extended-release tablets	alfuzosin	Elevated detrusor leak point pressure of neurologic origin	2-16 years	1	Pharmacokinetic	Open-label/Parallel group	29	6	2	B

12/15/2010	Uroxatral extended-release tablets	alfuzosin	Elevated detrusor leak point pressure of neurologic origin	2-16 years	2	Efficacy/Safety	Blind/Placebo/Parallel Group	172	49	15	B
12/15/2010	Uroxatral extended-release tablets	alfuzosin	Elevated detrusor leak point pressure of neurologic origin	2-16 years	3	Efficacy/Safety	Open-label	25	13	8	B
11/19/2010	Moxeza ophthalmic solution	moxifloxacin	Bacterial conjunctivitis	1 month & older	1	Efficacy/Safety	Blind/Placebo/Parallel Group	420	32	1	P
11/19/2010	Moxeza ophthalmic solution	moxifloxacin	Bacterial conjunctivitis	1 month & older	2	Efficacy/Safety	Blind/Active Control/Parallel Group	96	25	1	P
11/10/2010	Vyvanse	lisdexamfetamine	ADHD	13-17 years	1	Efficacy/Safety	Blind/Placebo/Parallel Group	314	45	1	P
11/10/2010	Vyvanse	lisdexamfetamine	ADHD	13-17 years	2	Efficacy/Safety	Open Label	269	45	1	P
11/2/2010	Ofirmev Injection	acetaminophen	Management of mild-to-moderate pain, for the management of moderate-to-severe pain with adjunctive opioid analgesics, and for the reduction of fever	0 - 17 year olds	1	Efficacy/Safety/Tolerability	Blind/Active Control/Parallel Group	183	18	1	P
11/2/2010	Ofirmev Injection	acetaminophen	Management of mild-to-moderate pain, for the management of moderate-to-severe pain with adjunctive opioid analgesics, and for the reduction of fever	0 - 17 year olds	2	Efficacy	Blind/Active Control	67	11	1	P

11/2/2010	Ofirmev Injection	acetaminophen	Management of mild-to-moderate pain, for the management of moderate-to-severe pain with adjunctive opioid analgesics, and for the reduction of fever	0 - 17 year olds	3	Safety	Open Label	100	12	1	P
11/2/2010	Ofirmev Injection	acetaminophen	Management of mild-to-moderate pain, for the management of moderate-to-severe pain with adjunctive opioid analgesics, and for the reduction of fever	0 - 17 year olds	4	Safety/PK	Open Label/Pop PK	81	5	1	P
10/5/2010	Aridol Powder for Inhalation	mannitol	Assessment of bronchial hyperresponsiveness	6-17 years	1	Efficacy/Safety	Open Label/Crossover	144	12	1	P
10/5/2010	Aridol Powder for Inhalation	mannitol	Assessment of bronchial hyperresponsiveness	6-17 years	2	Efficacy/Safety	Blind	111	25	1	P
10/5/2010	Aridol Powder for Inhalation	mannitol	Assessment of bronchial hyperresponsiveness	6-17 years	3	Pharmacokinetic/Pharmacodynamic	Open Label/Trad PK	23	1	1	P
9/28/2010	Kapvay Extended Release Tablets	clonidine	Treatment of attention deficit hyperactivity disorder (ADHD) as monotherapy and as adjunctive therapy	6-17 years	1	Efficacy/Safety	Blind/Placebo/Parallel Group	236	15	1	P
9/28/2010	Kapvay Extended Release Tablets	clonidine	Treatment of attention deficit hyperactivity disorder (ADHD) as monotherapy and as adjunctive therapy	6-17 years	2	Efficacy/Safety	Blind/Placebo/Parallel Group	197	22	1	P

9/28/2010	Kapvay Extended Release Tablets	clonidine	Treatment of attention deficit hyperactivity disorder (ADHD) as monotherapy and as adjunctive therapy to stimulant therapy	6-17 years	3	Safety	Open Label	303	27	1	P
8/27/2010	Augmentin XR	amoxicillin/clavulanate potassium	Community-acquired pneumonia or acute bacterial sinusitis	Adolescents <= 16 years old	1	Pharmacokinetic	Open Label/Traditional PK	44	6	1	P
7/28/2010	Lastacast Ophthalmic Solution	alcaftadine	Prevention of itching associated with allergic conjunctivitis.	Children >2 years old	1	Efficacy/Safety	Blind/Placebo	6	1	1	P
7/28/2010	Lastacast Ophthalmic Solution	alcaftadine	Prevention of itching associated with allergic conjunctivitis.	Children >2 years old	2	Efficacy/Safety	Blind/Placebo	11	5	1	P
7/28/2010	Lastacast Ophthalmic Solution	alcaftadine	Prevention of itching associated with allergic conjunctivitis.	Children >2 years old	3	Efficacy/Safety	Blind/Placebo	9	2	1	P
7/28/2010	Lastacast Ophthalmic Solution	alcaftadine	Prevention of itching associated with allergic conjunctivitis.	Children >2 years old	4	Safety	Blind/Placebo/Parallel Group	114	7	1	P
7/28/2010	Lastacast Ophthalmic Solution	alcaftadine	Prevention of itching associated with allergic conjunctivitis.	Children >2 years old	5	Efficacy/Safety	Blind/Placebo/Parallel Group	27	14	1	P
6/29/2010	Daytrana 10mg/9hr, 15mg/9hr, 20mg/9hr, 30mg/9hr transdermal systems	methylphenidate	Treatment of Attention Deficit and Hyperactivity Disorder (ADHD) in adolescent ages 13 to 17 years	6 - 17 years	1	Efficacy/Safety	Blind/Placebo/Parallel Group	217	32	1	P
6/29/2010	Daytrana 10mg/9hr, 15mg/9hr, 20mg/9hr, 30mg/9hr transdermal systems	methylphenidate	Treatment of Attention Deficit and Hyperactivity Disorder (ADHD) in adolescent ages 13 to 17 years	6 - 17 years	2	Safety	Open Label	162	30	1	P

6/29/2010	Daytrana 10mg/9hr, 15mg/9hr, 20mg/9hr, 30mg/9hr transdermal	methylphenidate	Treatment of Attention Deficit and Hyperactivity Disorder (ADHD) in adolescent ages 13 to 17 years	6 - 17 years	3	Pharmacokinetic	Open Label/Traditional Pharmacokinetic	71	4	1	P
6/22/2010	Dulera	mometasone furoate and formoterol fumarate	Treatment of asthma	12 years and older	1	Efficacy/Safety	Blind/Placebo/Paralle l Group	110	172	18	P
6/22/2010	Dulera	mometasone furoate and formoterol fumarate	Treatment of asthma	12 years and older	2	Efficacy/Safety	Blind/Placebo/Paralle l Group	63	152	17	P
6/22/2010	Dulera	mometasone furoate and formoterol fumarate	Treatment of asthma	12 years and older	3	Efficacy/Safety	Blind/Parallel Group	63	115	13	P
6/22/2010	Dulera	mometasone furoate and formoterol fumarate	Treatment of asthma	12 years and older	4	Safety	Open Label/Active Control	62	27	6	P
6/22/2010	Dulera	mometasone furoate and formoterol fumarate	Treatment of asthma	12 years and older	5	Efficacy/Safety	Open Label	42	56	1	P
6/22/2010	Dulera	mometasone furoate and formoterol fumarate	Treatment of asthma	12 years and older	6	Efficacy/Safety	Open Label/Active Control	40	164	17	P
6/3/2010	Zylet	loteprednol etabonate and tobramycin	Eye lid inflammation	0 - 6 years	1	Efficacy/Safety	Placebo/Blind	108	15	1	P
5/26/2010	Nasonex	mometasone	Nasal congestion associated with seasonal allergic rhinitis	2 years and older	1	Efficacy	Blind/Placebo/Paralle l Group	15	24	1	P

5/26/2010	Nasonex	mometasone	Nasal congestion associated with seasonal allergic rhinitis	2 years and older	2	Efficacy	Blind/Placebo/Parallel Group	25	24	1	P
5/26/2010	Nasonex	mometasone	Nasal congestion associated with seasonal allergic rhinitis	2 years and older	3	Efficacy	Blind/Placebo/Parallel Group	28	24	1	P
5/18/2010	Zymaxid	gatifloxacin	Bacterial conjunctivitis	1 year and older	1	Efficacy/Safety	Blind/Parallel Group	244	51	1	P
5/18/2010	Zymaxid	gatifloxacin	Bacterial conjunctivitis	1 year and older	2	Efficacy/Safety	Blind/Parallel Group	139	39	2	P
5/13/2010	Taxotere	docetaxel	Solid tumors	1 - 22 years	1	Pharmacokinetic/Tolerability	Open Label/Population Pharmacokinetic	61	16	1	B
5/13/2010	Taxotere	docetaxel	Solid tumors	1 - 26 years	2	Efficacy/Safety	Open Label	178	46	3	B
5/13/2010	Taxotere	docetaxel	Solid tumors	9 - 21 years	3	Efficacy/Safety	Open Label	75	26	14	B
4/12/2010	Pancreaze	pancrelipase	Treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions	1-17 years old	1	Efficacy/Safety/Tolerability	Blind/Placebo	14	12	2	P
4/12/2010	Pancreaze	pancrelipase	Treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions	1-17 years old	2	Efficacy/Safety	Blind/Parallel Group	18	5	2	P
3/24/2010	Viread	tenofovir disoproxil fumarate	Treatment of HIV infection in combination with other antiretroviral agents	12 - <18 years	1	Efficacy/Safety	Blind/Placebo/Parallel Group	87	18	2	B, P
3/17/2010	Differin Lotion	adapalene	Treatment of acne vulgaris	12 years & older	1	Efficacy/Safety	Blind/Parallel Group	670	39	2	P

3/17/2010	Differin Lotion	adapalene	Treatment of acne vulgaris	12 years & older	2	Efficacy/Safety	Blind/Parallel Group	674	36	2	P
3/17/2010	MultiHance Injection	gadobenate dimeglumine	Visualize lesions with abnormal blood brain barrier or abnormal vascularity of the brain, spine, and associated tissues		1	Efficacy/Safety	Open Label	94	17	6	P
3/17/2010	MultiHance Injection	gadobenate dimeglumine	Visualize lesions with abnormal blood brain barrier or abnormal vascularity of the brain, spine, and associated tissues		2	Safety/Pharmacokinetic	Open Label/Traditional PK	15	1	1	P
2/24/2010	Prevnar 13	Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein)	Active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F, and for the prevention of otitis media caused by serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F	6 weeks – 5 years	1	Safety/Immunogenicity	Randomized, Controlled, Observer Blind	663	38	1	P

2/24/2010	Prevnar 13	Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein)	Active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F, and for the prevention of otitis media caused by serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F	2 – 15 months	2	Safety/Immunogenicity	Open Label, Controlled, Randomized	1699	80	1	P
2/24/2010	Prevnar 13	Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein)	Active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F, and for the prevention of otitis media caused by serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F	7 - < 72 months	3	Safety/Immunogenicity	Non-Randomized, Non-Controlled, Open-Label	354	9	1	P

2/24/2010	Pprevnar 13	Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein)	Active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F, and for the prevention of otitis media caused by serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F	15 months-17 years	4	Safety/ Tolerability/ Immunogenicity	Open-Label	307*	32	1	P
2/24/2010	Pprevnar 13	Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein)	Active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F, and for the prevention of otitis media caused by serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F	6 weeks – 5 years	5	Safety/ Tolerability/ Immunogenicity	Randomized/Double-Blind/ Controlled	247	19	1	P
2/22/2010	Tamiflu	oseltamivir	Treatment (for those who have been symptomatic for no more than 2 days) & prophylaxis of influenza	1-12 years	1	Efficacy/Safety	Open Label	52	4	2	P
2/19/2010	Menveo	Meningococcal [Groups A, C, Y, and W 135] Oligosaccharide Diphtheria CRM197 Conjugate Vaccine	Active immunization to prevent invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y and W-135	11 – 55 years	1	Safety/Immunogenicity	Randomized, Controlled, Observer Blind,	2180	44	1	P

2/19/2010	Menveo	Meningococcal [Groups A, C, Y, and W 135] Oligosaccharide Diphtheria CRM197 Conjugate Vaccine	Active immunization to prevent invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y and W-135	11 – 18 years	2	Safety/Immunogenicity	Open Label, Controlled, Randomized	1620	1	1	P
2/19/2010	Menveo	Meningococcal [Groups A, C, Y, and W 135] Oligosaccharide Diphtheria CRM197 Conjugate Vaccine	Active immunization to prevent invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y and W-135	11 – 25 years	3	Safety/Immunogenicity	Randomized, Controlled, Observer Blind	944	14	1	P
2/19/2010	Menveo	Meningococcal [Groups A, C, Y, and W 135] Oligosaccharide Diphtheria CRM197 Conjugate Vaccine	Active immunization to prevent invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y and W-135	11 – 17 years	4	Safety/Immunogenicity	Randomized, Controlled, Single Blind	190	3	1	P
2/4/2010	Benicar	olmesartan	Hypertension in 6 years and older	1-16 years	1	Efficacy/Safety/Pharmacokinetic	Blind/Placebo/Parallel Group	362	65	4	B, P
2/4/2010	Benicar	olmesartan	Hypertension in 6 years and older	1-16 years	2	Pharmacokinetic	Open-label/Population Pharmacokinetic	24	6	1	B, P
1/29/2010	Lamictal XR Extended-Release tablets, 25mg, 50mg, 100mg, and 200mg	lamotrigine	Adjunctive therapy for Primary Generalized Tonic-Clonic (PGTC) seizures	13 years and older	1	Efficacy/Safety/Pharmacokinetic	Blind/Parallel Group	19	51	10	P

1/4/2010	Xolair	omalizumab	Moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.	6-11 years	1	Efficacy/Safety/Pharmacokinetic/Pharmacodynamic	Blind/Placebo/Population	628	87	7	P
1/4/2010	Xolair	omalizumab	Moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.	6-11 years	2	Safety/Tolerability	Blind/Placebo	334	27	1	P
12/24/2009	Famvir	famciclovir	Treatment of children 1 month – 12 years of age w/ herpes simplex (HSV) & 1 – 12 years w/ varicella zoster (VSV)	1 month - 12 years	1	Safety/Pharmacokinetic	Open Label/Population Pharmacokinetic	47	6	6	B, P
12/24/2009	Famvir	famciclovir	Treatment of children 1 month – 12 years of age w/ herpes simplex (HSV) & 1 – 12 years w/ varicella zoster (VSV)	1 month - 12 years	2	Safety/Pharmacokinetic	Open Label/Population Pharmacokinetic	53	6	6	B, P
12/24/2009	Famvir	famciclovir	Treatment of children 1 month – 12 years of age w/ herpes simplex (HSV) & 1 – 12 years w/ varicella zoster (VSV)	1 month - <1 year	3	Safety/Pharmacokinetic	Open Label/Population Pharmacokinetic	18	10	3	B, P

12/22/2009	Famvir	famciclovir	Treatment of elevated detrusor leak point pressure associated with neurological disorder	2-16 years	1	Efficacy/Safety/Pharmacokinetic	Blind/Placebo/Parallel Group/Population Pharmacokinetic	161	3	3	B
12/22/2009	Flomax	tamsulosin	Treatment of elevated detrusor leak point pressure associated with neurological disorder	2-16 years	2	Safety/Pharmacokinetic/Pharmacodynamic	Open Label/Population Pharmacokinetic	30	1	1	B
12/22/2009	Topamax	topiramate	Migraine Prophylaxis	12 years and older	1	Efficacy/Safety	Blind/Placebo	141	34	9	P
12/22/2009	Topamax	topiramate	Adjunctive Treatment for Partial Onset Epilepsy in Infants and Toddlers	1-24 months	1	Pharmacokinetic/Tolerability	Open Label/Population Pharmacokinetic	55	NR	NR	B
12/22/2009	Topamax	topiramate	Adjunctive Treatment for Partial Onset Epilepsy in Infants and Toddlers	1-24 months	3	Safety/Pharmacokinetic/Tolerability	Open Label	284	74	25	B
12/14/2009	Daytrana 10mg/9hr, 15mg/9hr, 20mg/9hr, 30mg/9hr transdermal systems	methylphenidate	Attention Deficit Hyperactivity Disorder- Postmarketing Study	6-12 years	1	Safety	Open Label	305	30	1	P
12/2/2009	Seroquel	quetiapine	Treatment of schizophrenia in adolescents 13 to 17 years of age and the treatment of bipolar mania in children and adolescents 10 to 17 years of age	10 - 17 years	1	Pharmacokinetic/Safety/Tolerability	Open Label	27	4	1	B, P

12/2/2009	Seroquel	quetiapine	Treatment of schizophrenia in adolescents 13 to 17 years of age and the treatment of bipolar mania in children and adolescents 10 to 17 years of age	10 - 17 years	2	Efficacy/Safety	Parallel Group/Blind/Placebo	220	46	10	B, P
12/2/2009	Seroquel	quetiapine	Treatment of schizophrenia in adolescents 13 to 17 years of age and the treatment of bipolar mania in children and adolescents 10 to 17 years of age	10 - 17 years	3	Efficacy/Safety	Parallel Group/Blind/Placebo	277	34	1	B, P
12/2/2009	Seroquel	quetiapine	Treatment of schizophrenia in adolescents 13 to 17 years of age and the treatment of bipolar mania in children and adolescents 10 to 17 years of age	10 - 17 years	4	Safety/Tolerability	Open Label	380	59	11	B, P
12/1/2009	Patanase Nasal Spray	olopatadine hydrochloride	Symptoms of seasonal allergic rhinitis	2-11 years	1	Efficacy/Safety 6 to <12 years	Blind/Placebo/Parallel Group	1188	173	1	B, P
12/1/2009	Patanase Nasal Spray	olopatadine hydrochloride	Symptoms of seasonal allergic rhinitis	2-11 years	2	Safety/Pharmacokinetic in 2 to <6 years	Blind/Placebo/Parallel Group\Population Pharmacokinetic	132	9	1	B, P
11/19/2009	Abilify	aripiprazole	Irritability associated with autistic disorder	6-17 years	1	Efficacy/Safety/Tolerability	Blind/Placebo/Parallel Group	164	20	1	P
11/19/2009	Abilify	aripiprazole	Irritability associated with autistic disorder	6-17 years	2	Efficacy/Safety/Tolerability	Blind/Placebo/Parallel Group	368	37	1	P
							Pharmacokinetic				

11/12/2009	Protonix	pantoprazole	GERD	0-16 years	2	Safety/Pharmacokinetic/Pharmacodynamic	Open label/Population Pharmacokinetic	67	9	3	B, P
11/12/2009	Protonix	pantoprazole	GERD	0-16 years	3	Efficacy / Safety	Open label/Randomized/Blinded/Placebo controlled	129	31	7	B, P
11/12/2009	Protonix	pantoprazole	GERD	0-16 years	4	Efficacy/Safety/Pharmacokinetic	Randomized/Traditional Pharmacokinetic	113	26	1	B, P
11/12/2009	Protonix	pantoprazole	GERD	0-16 years	5	Safety/Pharmacokinetic	Open label/Traditional Pharmacokinetic	136	35	1	B, P
11/10/2009	Afluria	Influenza Virus Vaccine	Active immunization of individuals 6 months through 17 of age against influenza virus subtypes A and B present in the vaccine	6 months – 17 years	1	Safety/Immunogenicity	Open Label	298	2	1	P
10/23/2009	Focalin XR extended-release capsules 5 mg, 10 mg, 20 mg, and 30 mg	dexmethylphenidate HCL	Treatment of Attention Deficit Hyperactivity Disorder	6 years and older	1	Efficacy/Safety/Tolerability	Blind/Placebo/Parallel Group	253	34	1	P
10/22/2009	Atacand	candesartan	Hypertension	1-17 years	1	Efficacy/Safety/Pharmacokinetic	Blind/Placebo/Parallel Group	240	27	8	B
10/22/2009	Atacand	candesartan	Hypertension	1-17 years	2	Efficacy/Safety/Pharmacokinetic	Open Label	235	27	8	B
10/22/2009	Atacand	candesartan	Hypertension	1-17 years	3	Efficacy/Safety/Pharmacokinetic	Blind/Placebo/Parallel Group	93	1	1	B

10/19/2009	Flurarix	Influenza Virus Vaccine	Active immunization for the prevention of disease caused by virus types A and B contained in the vaccine. (FLUARIX is approved for use in persons 3 years of age and older.)	6 months - <18 years	1	Safety/ immunogenicity	Blind/ Randomized/ Non-inferiority to competitor	3,325*	Multiple	1	P
10/16/2009	Cervarix	Human Papillomavirus Vaccine, AS04 Adjuvant-Adsorbed	Cervical cancer vaccine indicated for active immunization	10-14 years	1	Safety/Immunogenicity	Randomized/ Controlled/ Double-blind	2,067	57	12	P
10/16/2009	Cervarix	Human Papillomavirus Vaccine, AS04 Adjuvant-Adsorbed	Cervical cancer vaccine indicated for active immunization	10-25 years	2	Safety/Immunogenicity	Randomized/ Uncontrolled/ Blind/ Double-blind	770*	17	6	P
10/16/2009	Cervarix	Human Papillomavirus Vaccine, AS04 Adjuvant-Adsorbed	Cervical cancer vaccine indicated for active immunization	10-25 years	3	Safety/Immunogenicity/ Efficacy	Randomized/ Controlled/ Double-blind	1,113*	32	3	P
10/16/2009	Cervarix	Human Papillomavirus Vaccine, AS04 Adjuvant-Adsorbed	Cervical cancer vaccine indicated for active immunization	10-25 years	4	Safety/Immunogenicity/ Efficacy	Randomized/ Controlled/ Double-blind	18,665*	135	14	P
10/16/2009	Gardasil	Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine	Prevention of genital warts caused by HPV 6 and 11	9-26 years	1	Safety/Immunogenicity	Randomized, double-blind, controlled	1,364	Multiple	Multiple	P
10/15/2009	Crestor	rosuvastatin	Heterozygous familial hypercholesterolemia	10-17 years	1	Efficacy/Safety	Blind/Placebo/Parallel Group	173	20	5	B, P

10/2/2009	Welchol	colesevelam	Heterozygous familial hypercholesterolemia	10-17 years	1	Efficacy/Safety	Blind/Placebo/Parallel Group	194	41	12	B.P
9/8/2009	Bepreve 1.5%	bepotastine besilate ophthalmic solution	Treatment of itching associated with allergic conjunctivitis	10 years and older	1	Safety	Blind/Placebo/Parallel Group	127	6	1	P
9/2/2009	Intuniv extended-release 1 mg, 2 mg, 3 mg, & 4 mg tablets	guanfacine	Treatment of Attention Deficit Hyperactivity Disorder (ADHD)	6-17 years	1	Efficacy/Safety	Blind/Placebo/Parallel Group	345	48	1	P
9/2/2009	Intuniv extended-release 1 mg, 2 mg, 3 mg, & 4 mg tablets	guanfacine	Treatment of Attention Deficit Hyperactivity Disorder (ADHD)	6-17 years	2	Efficacy/Safety	Blind/Placebo/Parallel Group	324	51	1	P
9/2/2009	Intuniv extended-release 1 mg, 2 mg, 3 mg, & 4 mg tablets	guanfacine	Treatment of Attention Deficit Hyperactivity Disorder (ADHD)	6-17 years	3	Efficacy/Safety/Tolerability/PK/PD	Blind/Placebo/Traditional Pharmacokinetic	182	9	1	P
9/2/2009	Intuniv extended-release 1 mg, 2 mg, 3 mg, & 4 mg tablets	guanfacine	Treatment of Attention Deficit Hyperactivity Disorder (ADHD)	6-17 years	4	Pharmacokinetic	Open Label/Traditional Pharmacokinetic	28	1	1	P
9/2/2009	Intuniv extended-release 1 mg, 2 mg, 3 mg, & 4 mg tablets	guanfacine	Treatment of Attention Deficit Hyperactivity Disorder (ADHD)	6-17 years	5	Safety/Tolerability/Pharmacokinetic	Open Label/Traditional Pharmacokinetic	20	1	1	P
9/2/2009	Intuniv extended-release 1 mg, 2 mg, 3 mg, & 4 mg tablets	guanfacine	Treatment of Attention Deficit Hyperactivity Disorder (ADHD)	6-17 years	6	Efficacy/Safety/Tolerability	Open Label	75	17	1	P

9/2/2009	Intuniv extended-release 1 mg, 2 mg, 3 mg, & 4 mg tablets	guanfacine	Treatment of Attention Deficit Hyperactivity Disorder (ADHD)	6-17 years	7	Efficacy/Safety/Tolerability	Open Label	240	45	1	P
9/2/2009	Intuniv extended-release 1 mg, 2 mg, 3 mg, & 4 mg tablets	guanfacine	Treatment of Attention Deficit Hyperactivity Disorder (ADHD)	6-17 years	8	Efficacy/Safety/Tolerability	Open Label	262	48	1	P
9/2/2009	Intuniv extended-release 1 mg, 2 mg, 3 mg, & 4 mg tablets	guanfacine	Treatment of Attention Deficit Hyperactivity Disorder (ADHD)	6-17 years	9	Safety/Tolerability	Open Label	20	1	1	P
9/2/2009	Intuniv extended-release 1 mg, 2 mg, 3 mg, & 4 mg tablets	guanfacine	Treatment of Attention Deficit Hyperactivity Disorder (ADHD)	6-17 years	10	Efficacy/Safety	Blind/Placebo/Parallel Group	55	5	2	P
8/31/2009	Astepro Nasal Spray	azelastine hydrochloride 0.15% w/v	Relief of the symptoms of seasonal and perennial allergic rhinitis	12 years and older	1	Efficacy/Safety	Blind/Placebo	617	30	1	P
8/31/2009	Astepro Nasal Spray	azelastine hydrochloride 0.15% w/v	Relief of the symptoms of seasonal and perennial allergic rhinitis	12 years and older	2	Efficacy/Safety	Blind/Placebo	526	30	1	P
8/31/2009	Astepro Nasal Spray	azelastine hydrochloride 0.15% w/v	Relief of the symptoms of seasonal and perennial allergic rhinitis	12 years and older	3	Efficacy/Safety	Blind/Placebo	481	21	1	P
8/31/2009	Astepro Nasal Spray	azelastine hydrochloride 0.15% w/v	Relief of the symptoms of seasonal and perennial allergic rhinitis	12 years and older	4	Efficacy/Safety	Blind/Placebo	536	6	1	P

8/31/2009	Astepro Nasal Spray	azelastine hydrochloride 0.15% w/v	Relief of the symptoms of seasonal and perennial allergic rhinitis	12 years and older	5	Efficacy/Safety	Placebo	506	7	1	P
8/31/2009	Astepro Nasal Spray	azelastine hydrochloride 0.15% w/v	Relief of the symptoms of seasonal and perennial allergic rhinitis	12 years and older	6	Efficacy/Safety	Blind/Placebo	526	43	1	P
8/31/2009	Astepro Nasal Spray	azelastine hydrochloride 0.15% w/v	Relief of the symptoms of seasonal and perennial allergic rhinitis	12 years and older	7	Efficacy/Safety	Blind/Placebo	156	15	1	P
8/31/2009	Astepro Nasal Spray	azelastine hydrochloride 0.15% w/v	Relief of the symptoms of seasonal and perennial allergic rhinitis	12 years and older	8	Safety/Tolerability	Open Label/Active Control	547	57	1	P
8/28/2009	Valcyte	valganciclovir	Prevention of cytomegalovirus (CMV) disease in pediatric kidney and heart transplant patients	3 months - 16 years	1	Safety/Pharmacokinetic /Tolerability	Open Label/Traditional Pharmacokinetic	26	1	1	B, P
8/28/2009	Valcyte	valganciclovir	Prevention of cytomegalovirus (CMV) disease in pediatric kidney and heart transplant patients	6 months - 16 years	2	Safety/Pharmacokinetic	Open Label/Traditional Pharmacokinetic	20	1	1	B, P
8/28/2009	Valcyte	valganciclovir	Prevention of cytomegalovirus (CMV) disease in pediatric kidney and heart transplant patients	3 months - 16 years	3	Safety/Pharmacokinetic	Open Label/Traditional Pharmacokinetic	63	1	1	B, P
8/28/2009	Valcyte	valganciclovir	Treatment of cytomegalovirus (CMV) disease	neonates - 3 months	4	Pharmacokinetic/Pharmacodynamic	Open Label/Traditional Pharmacokinetic	24	1	1	B, P

8/27/2009	Zenpep Delayed-Release Capsules	pancrelipase	Treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions	1-17 years	1	Efficacy/Safety	Blind/Placebo/Crossover	22	12	1	P
8/27/2009	Zenpep Delayed-Release Capsules	pancrelipase	Treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions	1-17 years	2	Efficacy/Safety	Open Label	19	10	1	P
8/21/2009	Xyzal	levocetirizine	Seasonal allergic rhinitis (SAR) in children 2 years of age and older; perennial allergic rhinitis (PAR) and chronic idiopathic urticaria (CIU) for children 6 months of age and older	6 months and older	1	Pharmacokinetic	Open-label/Population Pharmacokinetic	181	1	1	B, P
8/21/2009	Xyzal	levocetirizine	Seasonal allergic rhinitis (SAR) in children 2 years of age and older; perennial allergic rhinitis (PAR) and chronic idiopathic urticaria (CIU) for children 6 months of age and older	6 months and older	2	Safety	Blinded	69	25	1	B, P
8/21/2009	Xyzal	levocetirizine	Seasonal allergic rhinitis (SAR) in children 2 years of age and older; perennial allergic rhinitis (PAR) and chronic idiopathic urticaria (CIU) for children 6 months of age and older	6 months and older	3	Safety	Blinded	173	29	1	B, P

8/19/2009	Hiberix	Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)	Active immunization for the prevention of invasive disease caused by Haemophilus influenzae type b when administered as a booster dose	15 -19 months	1	Immunogenicity	Open/ Randomized	64	4	1	P
8/19/2009	Hiberix	Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)	Active immunization for the prevention of invasive disease caused by Haemophilus influenzae type b	15 - 22 months	2	Immunogenicity	Open/ Randomized	138	1	1	P
8/19/2009	Hiberix	Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)	Active immunization for the prevention of invasive disease caused by Haemophilus influenzae type b when administered as a booster dose	15 - 18 months	3	Immunogenicity	Open	43	1	1	P
8/19/2009	Hiberix	Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)	Active immunization for the prevention of invasive disease caused by Haemophilus influenzae type b when administered as a booster dose	13-24 months	4	Safety	Open/ Randomized	375	45	1	P
7/31/2009	Xerese Cream	acyclovir/ hydrocortisone, 5%/1%	Early treatment of recurrent herpes labialis to reduce the likelihood of ulcerative cold sores & shorten the lesion healing time	12 years and older	1	Safety	Open Label	254	26	2	P
							Pharmacokinetic				

6/23/2009	Actonel	risedronate	Osteogenesis imperfecta	4-<16 years	2	Efficacy/Safety	Blind/Placebo/Parallel Group	143	20	5	B
6/18/2009	Nexium	esomeprazole	Short-term treatment of symptomatic GERD and erosive esophagitis	0-11 months	1	Safety/Pharmacokinetic/Pharmacodynamic	Open Label/Traditional Pharmacokinetic	26	1	1	B, P
6/18/2009	Nexium	esomeprazole	Short-term treatment of symptomatic GERD and erosive esophagitis	0-11 months	2	Safety/Pharmacokinetic/Pharmacodynamic	Blind/Traditional Pharmacokinetic	50	1	1	B, P
6/18/2009	Nexium	esomeprazole	Short-term treatment of symptomatic GERD and erosive esophagitis	0-11 months	3	Efficacy/Safety	Blind/Placebo/Parallel Group	80	25	4	B, P
5/29/2009	Lamictal XR Extended-Release tablets, 25mg, 50mg, 100mg, and 200mg	lamotrigine	Adjunctive therapy for partial onset seizures with or without secondary generalization	13 years and older	1	Efficacy/Safety/Tolerability/Pharmacokinetic	Parallel Group/Blind/Placebo/Population Pharmacokinetic	9	154	9	P
5/28/2009	Besivance 0.6%	besifloxacin ophthalmic suspension	Treatment of bacterial conjunctivitis	1 year and older	1	Efficacy/Safety	Parallel Group/Blind/Placebo	68	35	1	P
5/28/2009	Besivance 0.6%	besifloxacin ophthalmic suspension	Treatment of bacterial conjunctivitis	1 year and older	2	Efficacy/Safety	Parallel Group/Blind/Placebo	396	58	1	P
5/28/2009	Besivance 0.6%	besifloxacin ophthalmic suspension	Treatment of bacterial conjunctivitis	1 year and older	3	Efficacy/Safety	Parallel Group/Blind/Active Control	331	84	3	P
5/8/2009	Lamictal	lamotrigine	Adjunctive treatment for partial seizures	1-24 months	1	Efficacy/Safety/Pharmacokinetic	Blind/Placebo	177	14	14	B
5/8/2009	Lamictal	lamotrigine	Adjunctive treatment for partial seizures	1-24 months	2	Safety	Other	206	14	14	B

5/1/2009	Cetraxal 0.2%	ciprofloxacin otic solution	Treatment of acute otitis externa due to susceptible isolates of Pseudomonas aeruginosa or Staphylococcus aureus	1 year and older	1	Efficacy/Safety	Parallel Group/Blind/Active Control	336	47	2	P
4/30/2009	Axert	almotriptan	Acute treatment of pediatric migraine	12-17 years	1	Efficacy	Blind/Placebo/Parallel Group	714	93	4	B
4/30/2009	Axert	almotriptan	Acute treatment of pediatric migraine	12-17 years	2	Safety	Open label	447	53	1	B
4/30/2009	Creon	pancrelipase	Exocrine pancreatic insufficiency due to cystic fibrosis or other conditions	12-18 years	1	Efficacy/Safety	Blind/Placebo/Parallel Group	47	6	1	P
4/30/2009	Creon	pancrelipase	Exocrine pancreatic insufficiency due to cystic fibrosis or other conditions	12-18 years	2	Efficacy/Safety/Tolerability	Blind/Placebo/Crossover	11	10	1	P
4/30/2009	Creon	pancrelipase	Exocrine pancreatic insufficiency due to cystic fibrosis or other conditions	12-18 years	3	Efficacy/Safety	Blind/Placebo/Crossover	23	10	1	P
4/9/2009	Ulesfia Lotion, 5%	benzyl alcohol	Topical treatment of head lice infestation	6 months and older	1	Efficacy/Safety	Open Label/Parallel Group/Blind/Placebo/Active Control	66	1	1	P
4/9/2009	Ulesfia Lotion, 5%	benzyl alcohol	Topical treatment of head lice infestation	6 months and older	2	Efficacy/Safety	Open Label/Parallel Group/Blind/Placebo/Active Control	40	1	1	P
4/9/2009	Ulesfia Lotion, 5%	benzyl alcohol	Topical treatment of head lice infestation	6 months and older	3	Efficacy	Blind/Parallel Group/Dose Response	39	1	1	P
4/9/2009	Ulesfia Lotion, 5%	benzyl alcohol	Topical treatment of head lice infestation	6 months and older	4	Efficacy/Safety	Placebo/Blind	249	5	1	P
4/9/2009	Ulesfia Lotion, 5%	benzyl alcohol	Topical treatment of head lice infestation	6 months and older	5	Efficacy/Safety	Placebo/Blind	236	5	1	P
4/9/2009	Ulesfia Lotion, 5%	benzyl alcohol	Topical treatment of head lice infestation	6 months and older	6	Efficacy/Safety	Open Label	43	10	1	P

3/19/2009	Lexapro	escitalopram oxalate	Acute and maintenance treatment of major depressive disorder adolescents	12-17 years	1	Efficacy/Safety	Blind/Placebo/Parallel Group	312	40	1	B
3/19/2009	Lexapro	escitalopram oxalate	Acute and maintenance treatment of major depressive disorder adolescents	12-17 years	2	Efficacy/Safety	Blind/Placebo/Open Label/Parallel Group	202 - racial and ethnic data reported in study 1	35	1	B
3/19/2009	Lexapro	escitalopram oxalate	Acute and maintenance treatment of major depressive disorder adolescents	6-17 years	3	Efficacy/Safety	Blind/Placebo/Parallel Group	264	25	1	B
3/19/2009	Lexapro	escitalopram oxalate	Acute and maintenance treatment of major depressive disorder adolescents (citalopram)	12-17 years	4	Efficacy/Safety	Blind/Placebo/Parallel Group	174	21	1	B
3/19/2009	Lexapro	escitalopram oxalate	Acute and maintenance treatment of major depressive disorder adolescents (citalopram)	12-17 years	5	Efficacy/Safety	Blind/Placebo/Parallel Group	233	31	7	B
12/19/2008	Casodex Tablets 50 mg	bicalutamide	Precocious puberty in boys with testotoxicosis.	2 years and older	1	Efficacy	Open-label/Active Comparator/Parallel Group	14	10	3	B
12/18/2008	Prezista Tablet 75 mg, 300mg	darunavir	Treatment of HIV infection in pediatric patients 6 years and older when co-administered with ritonavir (Prezista/rtv), and with other antiretroviral agents	6 - <18 years	1	Safety/Pharmacokinetic	Open Label/Traditional Pharmacokinetic	80	12	9	B, P
12/11/2008	Epiduo Gel 0.1%/2.5%	adapalene and benzoyl peroxide	Topical treatment of acne vulgaris	12 years and older	1	Efficacy/Safety	Blind/Active Control/Parallel Group	1091	60	3	P

12/11/2008	Epiduo Gel 0.1%/2.5%	adapalene and benzoyl peroxide	Topical treatment of acne vulgaris	12 years and older	2	Efficacy/Safety	Blind/Active Control/Parallel Group	401	36	1	P
12/11/2008	Epiduo Gel 0.1%/2.5%	adapalene and benzoyl peroxide	Topical treatment of acne vulgaris	12 years and older	3	Efficacy/Safety	Open Label	299	29	1	P
12/11/2008	Epiduo Gel 0.1%/2.5%	adapalene and benzoyl peroxide	Topical treatment of acne vulgaris	12 years and older	4	Efficacy/Safety	Open Label/Parallel Group	150*	3	1	P
12/11/2008	Epiduo Gel 0.1%/2.5%	adapalene and benzoyl peroxide	Topical treatment of acne vulgaris	12 years and older	5	Efficacy/Safety/Tolerability	Blind/Placebo/Parallel Group	173	8	1	P
12/11/2008	PegIntron	Peginterferon alfa-2b	Treatment of chronic hepatitis C	3 - 17 years	1	Efficacy/Safety/Tolerability/Pharmacokinetics	Open Label/Traditional Pharmacokinetic	107	22	9	P
12/5/2008	Arimidex Tablet 1 mg	anastrozole	Gynecomastia in boys in 11-18 years of age and McCune-Albright Syndrome in girls less than or equal to 10 years of age	10 years and older	1	Efficacy/Safety	Blind/Placebo/Parallel Group	81	24	1	B
12/5/2008	Arimidex Tablet 1 mg	anastrozole	Gynecomastia in boys in 11-18 years of age and McCune-Albright Syndrome in girls less than or equal to 10 years of age	10 years and older	2	Efficacy/Safety	Open-label	28	14	7	B
12/5/2008	Arimidex Tablet 1 mg	anastrozole	Gynecomastia in boys in 11-18 years of age and McCune-Albright Syndrome in girls less than or equal to 10 years of age	10 years and older	3	Pharmacokinetic /Pharmacodynamic	Open-label/Traditional Pharmacokinetic	38	2	1	B
12/5/2008	Arimidex Tablet 1 mg	anastrozole	Gynecomastia in boys in 11-18 years of age and McCune-Albright Syndrome in girls less than or equal to 10 years of age	10 years and older	4	Pharmacokinetic	Open-label/Population Pharmacokinetic	64	2	2	B

11/14/2008	Neulasta	Pefilgrastim	Sarcoma	0 - 21 years	1	Safety/Pharmacokinetics	Open Label/Trad PK	44	10	2	P
10/28/2008	Prevacid	lansoprazole	GERD	0-11 months	1	Efficacy/Safety/Pharmacokinetic	Blind/Placebo/Parallel Group Traditional Pharmacokinetic/Pharmacodynamic	162	8	2	B, P
10/24/2008	Apidra	insulin glulisine [rDNA origin] injection	Improve glycemic control in adults and children with diabetes mellitus	4-17 years	1	Efficacy/Safety	Open Label/Parallel Group	572	65	16	P
10/24/2008	Apidra	insulin glulisine [rDNA origin] injection	Improve glycemic control in adults and children with diabetes mellitus	4-17 years	2	Safety/Pharmacokinetic/Pharmacodynamic	Blind/Traditional Pharmacokinetic/Crossover	20	1	1	P
10/23/2008	Acanya Gel	clindamycin/benzoyl peroxide	Topical treatment of acne vulgaris	12 years and older	1	Other	Blind/Placebo	705	12	1	P
10/23/2008	Acanya Gel	clindamycin/benzoyl peroxide	Topical treatment of acne vulgaris	12 years and older	2	Efficacy/Safety	Blind/Placebo/Parallel Group	850	35	3	P
10/23/2008	Acanya Gel	clindamycin/benzoyl peroxide	Topical treatment of acne vulgaris	12 years and older	3	Efficacy/Safety	Blind/Placebo/Parallel Group	905	33	1	P
10/23/2008	Acanya Gel	clindamycin/benzoyl peroxide	Topical treatment of acne vulgaris	12 years and older	4	Efficacy/Safety	Blind/Placebo/Parallel Group	285	14	1	P
10/10/2008	Kogenate FS	Antihemophilic Factor (Recombinant)	Routine prophylaxis to reduce the frequency of bleeding episodes and the risk of joint damage in children with hemophilia A with no pre-existing joint damage	0 – 2.5 years	1	Efficacy/Safety	Open Label/Blind/Parallel Group	65	14	1	P
9/19/2008	Nasacort AQ Nasal Spray	triamcinolone acetonide	Treatment of the nasal symptoms of seasonal and perennial allergic rhinitis in adults and children	2 years and older	1	Safety/Pharmacokinetic	Open Label/Traditional Pharmacokinetic	15	6	1	P

9/19/2008	Nasacort AQ Nasal Spray	triamcinolone acetonide	Treatment of the nasal symptoms of seasonal and perennial allergic rhinitis in adults and children	2 years and older	2	Safety	Placebo/Blind/Crossover	59	1	1	P
9/19/2008	Nasacort AQ Nasal Spray	triamcinolone acetonide	Treatment of the nasal symptoms of seasonal and perennial allergic rhinitis in adults and children	2 years and older	3	Efficacy/Safety	Blind/Placebo/Parallel Group	474	64	1	P
9/12/2008	Gardasil	Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine	Prevention of vulvar and vaginal cancer caused by HPV types 16 and 18	9-26 years	1	Efficacy / Safety / immuno-genicity	Random Controlled Trial	3,251	Multiple	Multiple	P
9/3/2008	Valtrex Caplets 500 mg and 1000 mg	valacyclovir	Herpes Virus Infection	1-<18 years	1	Safety/Pharmacokinetic /Tolerability	Open Label/Traditional Pharmacokinetic	57	15	4	B, P
9/3/2008	Valtrex Caplets 500 mg and 1000 mg	valacyclovir	Herpes Virus Infection	1-<18 years	2	Safety/Pharmacokinetic /Tolerability	Open Label/Traditional Pharmacokinetic	28	9	4	B, P
9/3/2008	Valtrex Caplets 500 mg and 1000 mg	valacyclovir	Herpes Virus Infection	1-<18 years	3	Safety/Pharmacokinetic /Tolerability	Open Label/Traditional Pharmacokinetic	27	7	4	B, P
8/28/2008	Zemuron Injection 10 mg/mL	rocuronium	Adjunct to general anesthesia	0-17 years	1	Efficacy/Safety	Blinded/Dose Response	189	19	2	B, P
8/28/2008	Zemuron Injection 10 mg/mL	rocuronium	Adjunct to general anesthesia	0-17 years	2	Safety/Pharmacokinetic /Pharmacodynamic	Open Label/Dose Response	137	23	3	B, P
8/14/2008	Zyprexa Tablets 2.5, 5, 7.5, 10, 15 20 mg	olanzapine	Bipolar Disorder; Schizophrenia (12/4/2009)	5-17 years	1	Efficacy/Safety	Blind/Parallel Group/Placebo	107	20	2	B
8/14/2008	Zyprexa Tablets 2.5, 5, 7.5, 10, 15 20 mg	olanzapine	Bipolar Disorder; Schizophrenia (12/4/2009)	5-17 years	2	Pharmacokinetic	Open label/Population Pharmacokinetic	107	22	2	B

8/14/2008	Zyprexa Tablets 2.5, 5, 7.5, 10, 15 20 mg	olanzapine	Bipolar Disorder; Schizophrenia (12/4/2009)	5-17 years	3	Safety/Pharmacokinetic	Open label	96	10	1	B
8/14/2008	Zyprexa Tablets 2.5, 5, 7.5, 10, 15 20 mg	olanzapine	Bipolar Disorder; Schizophrenia (12/4/2009)	5-17 years	4	Pharmacokinetic	Open Label/Traditional Pharmacokinetic	8	1	1	B
8/14/2008	Zyprexa Tablets 2.5, 5, 7.5, 10, 15 20 mg	olanzapine	Bipolar Disorder; Schizophrenia (12/4/2009)	5-17 years	5	Efficacy/Safety	Blind/Parallel Group/Placebo	161	25	1	B
8/14/2008	Zyprexa Tablets 2.5, 5, 7.5, 10, 15 20 mg	olanzapine	Bipolar Disorder; Schizophrenia (12/4/2009)	5-17 years	6	Efficacy/Safety	Open label	23	1	1	B
7/29/2008	Cancidas	caspofungin lyophilized powder for infusion 50 and 70 mg/m2	Aspergillosis and candida infections	2 - 17 years	1	Safety/Pharmacokinetic /Dose Response (1/3)	Open Label/Traditional Pharmacokinetic	39	8	1	B, P
7/29/2008	Cancidas	caspofungin lyophilized powder for infusion 50 and 70 mg/m2	Aspergillosis and candida infections	3 months - 17 years	2	Safety/Pharmacokinetic /Tolerability (2/3)	Open Label/Traditional Pharmacokinetic	9	5	1	B, P
7/29/2008	Cancidas	caspofungin lyophilized powder for infusion 50 and 70 mg/m2	Aspergillosis and candida infections	0-3 months	3	Safety/Pharmacokinetic /Tolerability (3/3)	Open Label/Traditional Pharmacokinetic	18	8	5	B, P
7/29/2008	Cancidas	caspofungin lyophilized powder for infusion 50 and 70 mg/m2	Aspergillosis and candida infections	3 months - 17 years	4	Efficacy/Safety/Tolerabi lity	Open Label	49	12	5	B, P
7/29/2008	Cancidas	caspofungin lyophilized powder for infusion 50 and 70 mg/m2	Aspergillosis and candida infections	2 - 17 years	5	Efficacy/Safety/Tolera bility	Blind/Placebo/Paralle l Group/	82	17	4	B, P

7/1/2008	Flovent HFA	fluticasone propionate	Asthma	6 - <12 months	1	Safety/Tolerability/PK/PD	Open Label/Trad PK	23	5	1	P
6/30/2008	Aciphex Delayed Release Tablets 20 mg	rabeprazole	GERD in adolescent patients	12 years and older	1	Efficacy/Safety	Open-label	111	25	1	B, P
6/30/2008	Aciphex Delayed Release Tablets 20 mg	rabeprazole	GERD in adolescent patients	12 years and older	2	Pharmacokinetic	Open-label/Traditional Pharmacokinetic	24	7	1	B, P
6/24/2008	Kinrix	Diphtheria and Tetanus Toxoids, Acellular Pertussis Vaccine Adsorbed and Poliovirus Vaccine Inactivated Combined	Active immunization against diphtheria, tetanus, pertussis and poliomyelitis as the fifth dose in the DTAP vaccine series and the fourth dose in the inactivated poliovirus vaccine (IPV) series	4 – 6 years	1	Safety/Immunogenicity	Open Label/ Randomized/ Active Control	4,209	24	2	P
6/24/2008	Kinrix	Diphtheria and Tetanus Toxoids, Acellular Pertussis Vaccine Adsorbed and Poliovirus Vaccine Inactivated Combined	Active immunization against diphtheria, tetanus, pertussis and poliomyelitis as the fifth dose in the DTAP vaccine series and the fourth dose in the inactivated poliovirus vaccine (IPV) series	4 – 6 years	2	Safety/Immunogenicity	Open Label/ Randomized/ Active Control	400	14	1	P

6/24/2008	Kinrix	Diphtheria and Tetanus Toxoids, Acellular Pertussis Vaccine Adsorbed and Poliovirus Vaccine Inactivated Combined	Active immunization against diphtheria, tetanus, pertussis and poliomyelitis as the fifth dose in the DTAP vaccine series and the fourth dose in the inactivated poliovirus vaccine (IPV) series	4 - 6 years	3	Safety/Immunogenicity	Open Label/ Randomized/ Active Control	362	3	1	P
6/24/2008	Viramune Tablets 200 mg & Oral Suspension 10 mg/ml	nevirapine	Use in combination with other antiretroviral agents for the treatment of HIV-1 infection	15 days - <16 years	1	Safety/Tolerability/Pharmacokinetic	Open Label/Traditional Pharmacokinetic	123	4	1	P
6/23/2008	Aptivus Capsule 250 mg, Solution 100 mg/mL	tipranavir	In combination with ritonavir in HIV-1 infected children	2-18 years	1	Safety/Pharmacokinetic/Tolerability	Open Label/Traditional Pharmacokinetic	110	24	8	B, P
6/20/2008	Kaletra Tablets 25 mg, 50 mg, 100 mg, 200 mg, Capsules 33.3 mg and 133.3 mg, Solution 20 mg/mL, 80 mg/dL	lopinavir/ritonavir	Use in combination with other antiretroviral agents for HIV-1 infection	14 days - 18 years	1	Safety/Pharmacokinetic/Tolerability	Open Label/Traditional Pharmacokinetic	31	17	2	B, P
6/20/2008	Kaletra Tablets 25 mg, 50 mg, 100 mg, 200 mg, Capsules 33.3 mg and 133.3 mg, Solution 20 mg/mL, 80 mg/dL	lopinavir/ritonavir	Use in combination with other antiretroviral agents for HIV-1 infection	14 days - 18 years	2	Efficacy/Safety/Pharmacokinetic/Tolerability	Open Label/Traditional Pharmacokinetic	26	15	1	B, P

6/20/2008	Kaletra Tablets 25 mg, 50 mg, 100 mg, 200 mg, Capsules 33.3 mg and 133.3 mg, Solution 20 mg/mL, 80 mg/dL	lopinavir/ritonavir	Use in combination with other antiretroviral agents for HIV-1 infection	14 days - 18 years	3	Efficacy/Safety/Pharma cokinetic/Tolerability	Open Label/Traditional Pharmacokinetic	100	10	6	B, P
6/20/2008	Pentacel	Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) Reconstituted with Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed Combined with Poliovirus Vaccine Inactivated	Active immunization against diphtheria, tetanus, pertussis, poliomyelitis and invasive disease due to Haemophilus influenzae type b	2 – 15 months	1	Safety/Immunogenicity	Randomized/ Controlled	3,538	16	1	P

6/20/2008	Pentacel	Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) Reconstituted with Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed Combined with Poliovirus Vaccine Inactivated	Active immunization against diphtheria, tetanus, pertussis, poliomyelitis and invasive disease due to Haemophilus influenzae type b	2 – 16 months	2	Safety/Immunogenicity	Randomized/ Controlled	1,207	11	1	P
6/20/2008	Pentacel	Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) Reconstituted with Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed Combined with Poliovirus Vaccine Inactivated	Active immunization against diphtheria, tetanus, pertussis, poliomyelitis and invasive disease due to Haemophilus influenzae type b	2 – 16 months	3	Safety/Immunogenicity	Randomized/ Controlled	2,357	31	1	P

6/20/2008	Pentacel	Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) Reconstituted with Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed Combined with Poliovirus Vaccine Inactivated	Active immunization against diphtheria, tetanus, pertussis, poliomyelitis and invasive disease due to Haemophilus influenzae type b	15-18 months	4	Safety/Immunogenicity	Randomized	1,782	7	1	P
6/20/2008	Pentacel	Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) Reconstituted with Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed Combined with Poliovirus Vaccine Inactivated	Active immunization against diphtheria, tetanus, pertussis, poliomyelitis and invasive disease due to Haemophilus influenzae type b	2 - 17 months	5	Safety/Immunogenicity	Randomized/ Open Label	1,257	38	1	P

6/5/2008	Zetia and Vytorin 6/13/2008	ezetimibe and ezetimibe/simvastatin	Heterozygous Familial Hypercholesterolemia	10-17 years	1	Efficacy/Safety	Blind/ Parallel Group/Active Control	246	47	2	B, P
5/9/2008	OraVerse Injection 0.4 mg (0.235 mg/mL)	phentolamine mesylate	Reversal of soft-tissue anesthesia, i.e., anesthesia of the lip and tongue, and the associated functional deficits resulting from an intraoral submucosal injection of a local anesthetic containing a vasoconstrictor	3 years and older	1	Efficacy/Safety/Pharmacodynamic	Blind/Placebo	31	18	1	P
5/9/2008	OraVerse Injection 0.4 mg (0.235 mg/mL)	phentolamine mesylate	Reversal of soft-tissue anesthesia, i.e., anesthesia of the lip and tongue, and the associated functional deficits resulting from an intraoral submucosal injection of a local anesthetic containing a vasoconstrictor	3 years and older	2	Efficacy/Safety/Pharmacodynamic	Blind/Placebo	24	16	1	P

5/9/2008	OraVerse Injection 0.4 mg (0.235 mg/mL)	phentolamine mesylate	Reversal of soft-tissue anesthesia, i.e., anesthesia of the lip and tongue, and the associated functional deficits resulting from an intraoral submucosal injection of a local anesthetic containing a vasoconstrictor	3 years and older	3	Efficacy/Safety	Blind/Placebo	152	11	1	P
5/9/2008	OraVerse Injection 0.4 mg (0.235 mg/mL)	phentolamine mesylate	Reversal of soft-tissue anesthesia, i.e., anesthesia of the lip and tongue, and the associated functional deficits resulting from an intraoral submucosal injection of a local anesthetic containing a vasoconstrictor	3 years and older	4	Efficacy/Safety	Blind/Placebo	26	7	1	P
5/9/2008	OraVerse Injection 0.4 mg (0.235 mg/mL)	phentolamine mesylate	Reversal of soft-tissue anesthesia, i.e., anesthesia of the lip and tongue, and the associated functional deficits resulting from an intraoral submucosal injection of a local anesthetic containing a vasoconstrictor	3 years and older	5	Safety/Pharmacokinetic	Open Label/Traditional Pharmacokinetic	19	3	1	P

5/8/2008	Desmopressin acetate Tablets, 0.1 mg and 0.2 mg	desmopressin acetate	Determine the capacity of the kidney to concentrate urine in pediatric patients (Renal Concentration Capacity Test or RCCT) and management of primary nocturnal enuresis (PNE)	3-18 years	1	Efficacy/Safety	Blind/Placebo	145	6	1	P
5/8/2008	Desmopressin acetate (desmopressin acetate) Tablets, 0.1 mg and 0.2 mg	desmopressin acetate	Determine the capacity of the kidney to concentrate urine in pediatric patients (Renal Concentration Capacity Test or RCCT) and management of primary nocturnal enuresis (PNE)	3-18 years	2	Efficacy/Safety	Open Label	58	2	1	P
5/8/2008	Desmopressin acetate (desmopressin acetate) Tablets, 0.1 mg and 0.2 mg	desmopressin acetate	Determine the capacity of the kidney to concentrate urine in pediatric patients (Renal Concentration Capacity Test or RCCT) and management of primary nocturnal enuresis (PNE)	3-18 years	3	Efficacy	Blind/Parallel Group	31	14	1	P

5/8/2008	Desmopressin acetate (desmopressin acetate) Tablets, 0.1 mg and 0.2 mg	desmopressin acetate	Determine the capacity of the kidney to concentrate urine in pediatric patients (Renal Concentration Capacity Test or RCCT) and management of primary nocturnal enuresis (PNE)	3-18 years	4	Efficacy	Blind/Crossover	23	1	1	P
5/8/2008	Desmopressin acetate (desmopressin acetate) Tablets, 0.1 mg and 0.2 mg	desmopressin acetate	Determine the capacity of the kidney to concentrate urine in pediatric patients (Renal Concentration Capacity Test or RCCT) and management of primary nocturnal enuresis (PNE)	3-18 years	5	Efficacy	Open Label	30	1	1	P
5/8/2008	Desmopressin acetate (desmopressin acetate) Tablets, 0.1 mg and 0.2 mg	desmopressin acetate	Determine the capacity of the kidney to concentrate urine in pediatric patients (Renal Concentration Capacity Test or RCCT) and management of primary nocturnal enuresis (PNE)	3-18 years	6	Efficacy	Open Label	38	11	1	P
5/8/2008	Desmopressin acetate (desmopressin acetate) Tablets, 0.1 mg and 0.2 mg	desmopressin acetate	Determine the capacity of the kidney to concentrate urine in pediatric patients (Renal Concentration Capacity Test or RCCT) and management of primary nocturnal enuresis (PNE)	3-18 years	7	Efficacy	Open Label	249	9	1	P

5/5/2008	Argatroban Injection 100 mg/mL	argatroban	Heparin-Induced Thrombocytopenia (HIT) or HIT with Thrombosis	0-16 years	1	Efficacy/Safety/Pharmacokinetic /Pharmacodynamic	Open Label/Traditional Pharmacokinetic	11	12	1	B, P
4/30/2008	Cardiolite Kit	technetium tc99m sestamibi	Myocardial perfusion imaging	4-17 years	1	Safety/ Pharmacokinetic	Open Label/Traditional Pharmacokinetic	78	10	3	B, P
4/30/2008	Cardiolite Kit	technetium tc99m sestamibi	Myocardial perfusion imaging	4-17 years	2	Efficacy/Safety	Blind/Placebo	445	51	8	B, P
4/30/2008	Cardiolite Kit	technetium tc99m sestamibi	Myocardial perfusion imaging	4-17 years	3	Efficacy/Safety	Other	86	19	5	B, P
4/15/2008	Patanase Nasal Spray	olopatadine hydrochloride	Relief of symptoms of seasonal allergic rhinitis (SAR)	12 years and older	1	Efficacy/Safety	Blind/Placebo/Parallel Group	32	33	1	P
4/15/2008	Patanase Nasal Spray	olopatadine hydrochloride	Relief of symptoms of seasonal allergic rhinitis (SAR)	12 years and older	2	Efficacy/Safety	Blind/Placebo/Parallel Group	28	7	1	P
4/15/2008	Patanase Nasal Spray	olopatadine hydrochloride	Relief of symptoms of seasonal allergic rhinitis (SAR)	12 years and older	3	Safety	Placebo/Parallel Group	72	43	1	P
4/15/2008	Patanase Nasal Spray	olopatadine hydrochloride	Relief of symptoms of seasonal allergic rhinitis (SAR)	12 years and older	4	Efficacy/Safety	Blind/Placebo/Parallel Group	19	7	1	P
4/15/2008	Patanase Nasal Spray	olopatadine hydrochloride	Relief of symptoms of seasonal allergic rhinitis (SAR)	12 years and older	5	Efficacy/Safety	Blind/Active Control/Placebo/Parallel Group	14	13	1	P
4/15/2008	Patanase Nasal Spray	olopatadine hydrochloride	Relief of symptoms of seasonal allergic rhinitis (SAR)	12 years and older	6	Efficacy/Safety	Blind/Active Control/Placebo	32	17	1	P

4/15/2008	Patanase Nasal Spray	olopatadine hydrochloride	Relief of symptoms of seasonal allergic rhinitis (SAR)	12 years and older	7	Efficacy	Blind/Active Control/Placebo/Parallel Group	9	1	1	P
4/15/2008	Patanase Nasal Spray	olopatadine hydrochloride	Relief of symptoms of seasonal allergic rhinitis (SAR)	12 years and older	8	Efficacy/Safety/Pharmacokinetic	Blind/Parallel Group/Traditional Pharmacokinetic	271	7	1	P
4/15/2008	Patanase Nasal Spray	olopatadine hydrochloride	Relief of symptoms of seasonal allergic rhinitis (SAR)	12 years and older	9	Safety	Blind/Placebo/Parallel Group	99	80	1	P
4/15/2008	Patanase Nasal Spray	olopatadine hydrochloride	Relief of symptoms of seasonal allergic rhinitis (SAR)	12 years and older	10	Efficacy/Safety	Blind/Placebo/Active Control/Parallel Group	51	21	1	P
4/7/2008	Orencia	abatacept	Treatment of moderate to severe polyarticular juvenile idiopathic arthritis (JIA)	6 years and older	1	Efficacy/Safety	Open Label/Blind/Placebo	190	45	11	P
4/3/2008	Rotarix	Rotavirus Vaccine, Live, Oral, Monovalent	Prevention of rotavirus gastroenteritis caused by G1 and non-G1 types (including G3, G4, and G9)	6 - 24 weeks	1	Efficacy/Safety/Immunogenicity	Randomized/ Double-blind/ Placebo-controlled	63,225	177	11	P
4/3/2008	Rotarix	Rotavirus Vaccine, Live, Oral, Monovalent	Prevention of rotavirus gastroenteritis caused by G1 and non-G1 types (including G3, G4, and G9)	6 - 24 weeks	2	Safety/ Immunogenicity	Double blind/ Randomized/ Placebo controlled	529	41	2	P
4/3/2008	Rotarix	Rotavirus Vaccine, Live, Oral, Monovalent	Prevention of rotavirus gastroenteritis caused by G1 and non-G1 types (including G3, G4, and G9)	6 - 24 weeks	3	Efficacy/ Safety/ Immunogenicity	double blind randomized placebo controlled	2,276	3	3	P

4/3/2008	Rotarix	Rotavirus Vaccine, Live, Oral, Monovalent	Prevention of rotavirus gastroenteritis caused by G1 and non-G1 types (including G3, G4, and G9)	6 - 24 weeks	4	Efficacy/ Safety/ Immunogenicity	double blind randomized placebo controlled	2,464	8	1	P
4/3/2008	Rotarix	Rotavirus Vaccine, Live, Oral, Monovalent	Prevention of rotavirus gastroenteritis caused by G1 and non-G1 types (including G3, G4, and G9)	6 - 24 weeks	5	Safety/ Immunogenicity	double blind randomized placebo controlled	854	7	3	P
4/3/2008	Rotarix	Rotavirus Vaccine, Live, Oral, Monovalent	Prevention of rotavirus gastroenteritis caused by G1 and non-G1 types (including G3, G4, and G9)	6 - 24 weeks	6	Efficacy/Safety/ Immunogenicity	Double blind/ Randomized/ Placebo controlled	3,994	87	6	P
4/3/2008	Rotarix	Rotavirus Vaccine, Live, Oral, Monovalent	Prevention of rotavirus gastroenteritis caused by G1 and non-G1 types (including G3, G4, and G9)	6 - 24 weeks	7	Safety/ Immunogenicity	Double blind/ Randomized/ Placebo controlled	450	2	1	P
4/3/2008	Rotarix	Rotavirus Vaccine, Live, Oral, Monovalent	Prevention of rotavirus gastroenteritis caused by G1 and non-G1 types (including G3, G4, and G9)	6 - 24 weeks	8	Safety/ Immunogenicity	Double blind/ Randomized/ Placebo controlled	250	5	1	P

3/31/2008	Lancôme UV EXPERT 40, La Roche-Posay ANTHELIOS 40, & Vichy CAPITAL SOLEIL 40	2% avobenzone, 3% ecamsule, 10% octocrylene and 5% titanium dioxide cream	Helps prevent sunburn; Higher SPF gives more sunburn protection; Helps provide protection from UVA rays (short and long wavelengths)	6 months - 12 years	1	Safety	Open Label	135	4	1	P
3/26/2008	Ventolin HFA Oral Inhalation Aerosol	albuterol	Treatment and prevention of bronchospasm	birth - less than 4 years	1	Efficacy/Safety	Blind/Placebo/Parallel Group	77	37	1	B
3/26/2008	Ventolin HFA Oral Inhalation Aerosol	albuterol	Treatment and prevention of bronchospasm	birth - less than 4 years	2	Efficacy/Safety	Blind/Placebo/Parallel Group	86	33	1	B
3/26/2008	Ventolin HFA Oral Inhalation Aerosol	albuterol	Treatment and prevention of bronchospasm	birth - less than 4 years	3	Efficacy/Safety	Blind/Parallel Group	87	16	1	B
3/25/2008	Reyataz	atazanavir	HIV	6 - < 18 years	1	Safety/Pharmacokinetic	Open Label/Traditional Pharmacokinetic	104	3	2	B, P
3/24/2008	Depakote ER Tablets 250, 500 mg and Sprinkles 125 mg Capsules	valproate	Migraine prophylaxis	12-17 years	1	Efficacy/Safety	Blind/Placebo/Parallel Group/Dose Response	304	38	1	B, P
3/24/2008	Depakote ER Tablets 250, 500 mg and Sprinkles 125 mg Capsules	valproate	Adolescent Bipolar Disorder in association with bipolar disorder	10-17 years	2	Efficacy	Blind/Placebo/Parallel Group	144	24	1	B, P
3/24/2008	Depakote ER Tablets 250, 500 mg and Sprinkles 125 mg Capsules	valproate	Partial seizures	3-10 years	3	Safety	Open-label	169	29	2	B, P

3/20/2008	Prilosec for Delayed-Release Oral Suspension	omeprazole	Maintenance healing of erosive esophagitis	0-2 years	1	Pharmacokinetic	Open Label/Traditional Pharmacokinetic	25	11	3	B, P
3/20/2008	Prilosec for Delayed-Release Oral Suspension	omeprazole	Maintenance healing of erosive esophagitis	0-2 years	2	Efficacy	Other	115	21	1	B, P
3/20/2008	Prilosec for Delayed-Release Oral Suspension	omeprazole	Maintenance healing of erosive esophagitis	0-2 years	3	Pharmacokinetic	Other	44	8	3	B, P
3/20/2008	Zometa Vial for Infusion 5 mg	zoledronic acid	Severe osteogenesis imperfecta	1-17 years	1	Pharmacokinetic	Open Label/Traditional Pharmacokinetic	11 - *subset of the 150 patients in study 2	5	3	B
3/20/2008	Zometa Vial for Infusion 5 mg	zoledronic acid	Severe osteogenesis imperfecta	1-17 years	2	Efficacy/Safety	Blind/ Parallel Group/Active Control	150	20	9	B
3/19/2008	Artiss	Fibrin Sealant (Human)	To adhere autologous skin grafts to surgically prepared wound beds resulting from burns in adult and pediatric populations.	1-16 years	1	Efficacy/Safety	Active Control/Blind	37	13	1	P
3/14/2008	NovoLog	insulin aspart [rDNA origin] injection	Insulin analog indicated to improve glycemic control	4-18 years	1	Efficacy/Safety	Open Label/Active Control/Parallel Group	298	45	1	P
3/14/2008	NovoLog	insulin aspart [rDNA origin] injection	Insulin analog indicated to improve glycemic control	4-18 years	2	Efficacy/Safety	Open Label/Active Control/Parallel Group	61	5	1	P
3/12/2008	Daptacel	Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed	Active immunization as a booster dose against diphtheria, tetanus & pertussis	6 weeks - 6 years	1	Safety/Immunogenicity	Open Label	649	22	1	P

2/27/2008	Nexium Delayed-Release Granules for Oral Suspension 10 mg	esomeprazole	Short-term treatment of symptomatic GERD and erosive esophagitis	1-11 years	1	Efficacy/Safety	Blind/Placebo/Parallel Group	109	24	1	B
2/27/2008	Nexium Delayed-Release Granules for Oral Suspension 10 mg	esomeprazole	Short-term treatment of symptomatic GERD and erosive esophagitis	1-11 years	2	Pharmacokinetic	Open Label/Traditional Pharmacokinetic	31	7	1	B
2/21/2008	Humira	adalimumab	Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis	4 years and older	1	Efficacy/Safety/Pharmacokinetics	Open Label/Blind/Placebo/Parallel Group/Population PK	171	31	8	P
2/1/2008	Asmanex Twisthaler 110mcg	mometasone furoate inhalation powder	Maintenance treatment of asthma as prophylactic therapy	4 years and older	1	Efficacy/Safety	Blind/Placebo/Parallel Group	296	39	6	P
2/1/2008	Asmanex Twisthaler 110mcg	mometasone furoate inhalation powder	Maintenance treatment of asthma as prophylactic therapy	4 years and older	2	Efficacy/Safety	Blind/Placebo/Parallel Group	349	25	1	P
2/1/2008	Asmanex Twisthaler 110mcg	mometasone furoate inhalation powder	Maintenance treatment of asthma as prophylactic therapy	4 years and older	3	Efficacy/Safety	Blind/Placebo/Parallel Group	290	20	6	P
2/1/2008	Asmanex Twisthaler 110mcg	mometasone furoate inhalation powder	Maintenance treatment of asthma as prophylactic therapy	4 years and older	4	Safety	Blind/Placebo/Parallel Group	50	1	1	P
2/1/2008	Asmanex Twisthaler 110mcg	mometasone furoate inhalation powder	Maintenance treatment of asthma as prophylactic therapy	4 years and older	5	Safety	Blind/Placebo/Parallel Group	187	29	1	P
2/1/2008	Asmanex Twisthaler 110mcg	mometasone furoate inhalation powder	Maintenance treatment of asthma as prophylactic therapy	4 years and older	6	Safety	Open Label/Active Control	233	21	1	P

2/1/2008	Asmanex Twisthaler 110mcg	mometasone furoate inhalation powder	Maintenance treatment of asthma as prophylactic therapy	4 years and older	7	Safety	Blind/Placebo/Crossover	23	1	1	P
2/1/2008	Asmanex Twisthaler 110mcg	mometasone furoate inhalation powder	Maintenance treatment of asthma as prophylactic therapy	4 years and older	8	Safety	Blind/Placebo/Active Control/Crossover	51	1	1	P
1/31/2008	Inspra Tablets 25, 50, 100 mg	eplerenone	Treatment of Hypertension	6-16 years	1	Efficacy/Safety	Blind/Placebo/Parallel Group/Dose Response	246	43	5	B.P
1/31/2008	Inspra Tablets 25, 50, 100 mg	eplerenone	Treatment of Hypertension	6-16 years	2	Safety/Pharmacokinetic	Open Label/Traditional Pharmacokinetic	149	20	3	B.P
1/31/2008	Inspra Tablets 25, 50, 100 mg	eplerenone	Treatment of Hypertension	6-16 years	3	Pharmacokinetic	Open Label/Traditional Pharmacokinetic	18	1	1	B.P
1/23/2008	Moxatag Extended-release Tablet, 775 mg	amoxicillin	Use for tonsillitis and/or pharyngitis secondary to Streptococcus pyogenes patients	12 years and older	1	Efficacy/Safety	Blind/Placebo/Parallel Group	142	64	1	P
1/23/2008	Moxatag Extended-release Tablet, 775 mg	amoxicillin	Use for tonsillitis and/or pharyngitis secondary to Streptococcus pyogenes patients	12 years and older	2	Efficacy/Safety	Blind/Placebo/Parallel Group	139	50	2	P
1/10/2008	Alvesco Inhalation Aerosol, 80 mcg & 160 mcg	ciclesonide	Treatment of asthma	4-11 years	1	Efficacy/Safety	Blind/Placebo/Parallel Group//Dose Response	514	67	2	P
1/10/2008	Alvesco Inhalation Aerosol, 80 mcg & 160 mcg	ciclesonide	Treatment of asthma	4-11 years	2	Efficacy/Safety/Dose Response	Blind/Placebo/Parallel Group	517	64	2	P
1/10/2008	Alvesco Inhalation Aerosol, 80 mcg & 160 mcg	ciclesonide	Treatment of asthma	12 years and older	3	Safety	Open Label	193	26	1	P

1/10/2008	Alvesco Inhalation Aerosol, 80 mcg & 160 mcg	ciclesonide	Treatment of asthma	12 years and older	4	Safety	Open Label	190	26	1	P
1/10/2008	Alvesco Inhalation Aerosol, 80 mcg & 160 mcg	ciclesonide	Treatment of asthma	4-11 years	5	Safety	Open Label	232	29	1	P
1/10/2008	Alvesco Inhalation Aerosol, 80 mcg & 160 mcg	ciclesonide	Treatment of asthma	12 years and older	6	Safety/Pharmacodynamic	Placebo	24	1	1	P
1/10/2008	Alvesco Inhalation Aerosol, 80 mcg & 160 mcg	ciclesonide	Treatment of asthma	12 years and older	7	Efficacy/Safety/Tolerability	Blind	728	51	1	P
1/2/2008	Evicel	Fibrin Sealant (Human)	An adjunct to hemostasis for use in patients undergoing surgery, when control of bleeding by standard surgical techniques is ineffective or impractical.	2-16 years (retroperitoneal and intra-abdominal surgery)	1	Efficacy/Safety	Active Control	4	18	1	P
1/2/2008	Evicel	Fibrin Sealant (Human)	An adjunct to hemostasis for use in patients undergoing surgery, when control of bleeding by standard surgical techniques is ineffective or impractical.	6 months – 16 years (liver surgery)	2	Efficacy/Safety	Active Control	8	15	1	P
12/27/2007	AndroGel Gel 1%	testosterone	Delayed puberty due to hypogonadism or constitutional delay of growth and puberty	13-18 years	1	Safety/Pharmacokinetic/Dose Response	Open-label	17	6	1	B

12/27/2007	AndroGel Gel 1%	testosterone	Delayed puberty due to hypogonadism or constitutional delay of growth and puberty	13-18 years	2	Efficacy/Safety	Open-label	86	18	1	B
12/27/2007	Voluven	6% Hydroxyethyl Starch 130/0.4 in 0.9% Sodium Chloride Injection	Treatment and prophylaxis of hypovolemia	newborns to infants < 2 years	1	Efficacy/Safety	Blind	41	6	1	P
12/19/2007	Hepsera Tablet 10 mg	adefovir	Chronic hepatitis B	2-18 years	1	Efficacy/Safety	Blind/Placebo/Parallel Group	173	26	6	B, P
12/19/2007	Hepsera Tablet 10 mg	adefovir	Chronic hepatitis B	2-18 years	2	Safety/ Pharmacokinetic	Open Label/Traditional Pharmacokinetic	45	10	1	B, P
12/12/2007	Derma-Smoother Topical Oil, 0.01% Body Oil	fluocinolone	Treatment of atopic dermatitis	3 months and older	1	Safety	Open Label	32	2	1	P
11/29/2007	Diovan 40, 80, 160, and 320 mg Tablets.	valsartan	Hypertension	1-16 years	1	Pharmacokinetic	Open Label/Traditional Pharmacokinetic	26	6	2	B
11/29/2007	Diovan 40, 80, 160, and 320 mg Tablets.	valsartan	Hypertension	1-16 years	2	Safety	Blind/Placebo/Parallel Group/Dose Response	261	55	9	B
11/29/2007	Diovan 40, 80, 160, and 320 mg Tablets.	valsartan	Hypertension	1-16 years	3	Safety	Blind/Placebo/Parallel Group/Dose Response	90	36	7	B
11/21/2007	Omnaris Nasal Spray	ciclesonide	Treatment of seasonal allergic rhinitis (SAR)	2-12 years	1	Safety/Tolerability	Blind/Placebo/Parallel Group	125	3	1	P
11/21/2007	Omnaris Nasal Spray	ciclesonide	Treatment of seasonal allergic rhinitis (SAR)	2-12 years	2	Efficacy/Safety	Blind/Placebo/Parallel Group	618	69	1	P
10/29/2007	Abilify Tablets 5/10/15/20/30 mg	aripiprazole	Bipolar Disorder; Schizophrenia (2/27/2008)	11- 17 years	1	Efficacy/Safety	Blind/Placebo/Parallel Group	296	59	1	B, P

10/29/2007	Abilify Tablets 5/10/15/20/30 mg	aripiprazole	Bipolar Disorder; Schizophrenia (2/27/2008)	11- 17 years	2	Pharmacokinetic	Open- label/Population Pharmacokinetic	21	1	1	B, P
10/29/2007	Abilify Tablets 5/10/15/20/30 mg	aripiprazole	Bipolar Disorder; Schizophrenia (2/27/2008)	11- 17 years	3	Efficacy/Safety	Blind/Placebo/Paralle l Group	302	101	13	B, P
10/29/2007	Abilify Tablets 5/10/15/20/30 mg	aripiprazole	Bipolar Disorder; Schizophrenia (2/27/2008)	11- 17 years	4	Safety/Tolerability	Open-label	325	152	13	B, P
9/28/2007	Lamisil Oral Granules, 125, 187.5 mg.	terbinafine	Tinea capitis	4-12 years	1	Pharmacokinetic	Open label/ Traditional	16	1	1	B
9/28/2007	Lamisil Oral Granules, 125, 187.5 mg.	terbinafine	Tinea capitis	4-12 years	2	Efficacy/Safety	Blind/Active Comparator/Parallel Group	747	74	7	B
9/28/2007	Lamisil Oral Granules, 125, 187.5 mg.	terbinafine	Tinea capitis	4-12 years	3	Efficacy/Safety	Blind/Active Comparator/Parallel Group	802	72	9	B

Total Number of FDAAA Assessments* = 130

Number of Assessments BPCA = 22

Number of Assessments PREA = 80

Number of Assessments BPCA + PREA = 28

*Assessments are studies containing data gathered using appropriate formulations for each age group for which studies are required that assess the safety and effectiveness of the product and support dosing and administration of the product in the pediatric population.

The table above contains pediatric assessments (or studies) made under sections 505B and 505A of the Federal Food, Drug, and Cosmetic Act (the Act), as amended by the FDA Amendments Act of 2007 (FDAAA). In accordance with sections 505B(f)(6) and 505A(f)(6) of the Act, as amended by FDAAA, the list identifies those products approved on or after September 27, 2007, that fell within the scope of the Pediatric Research Equity Act (PREA) and/or the Best Pharmaceuticals for Children Act, and contained new pediatric information.

This list specifically highlights the number of assessments (or studies) conducted under the sections referenced above, the specific drugs and their uses, and the types of assessments conducted, including trial design, number of pediatric patients studied, and the number of centers and countries involved.

Definitions of the specific study types and designs used in the table

* = Number includes pediatric and adult patients* The asterisk in “No of Patients” column indicates that the number of patients includes adults and children. If the number isn’t asterisked, the number represents the total number of pediatric patients only in the study.

Study Types

1. Efficacy: Efficacy studies are done to provide evidence of a drug’s ability to diagnosis, cure, mitigation, treatment, or prevention of a disease. Efficacy information may be found in the drug labeling Indications & Usage, Use in Specific Populations, and Clinical Studies sections.

2. Safety: Safety studies provide evidence of a drug’s medical risk to humans. Safety is usually determined by collecting information on laboratory and/or other tests (for example, electrocardiogram and vision), vital signs, and drug side effects. Safety information may be found in the drug labeling Warnings & Precautions, Adverse Reactions, and Use in Specific Populations sections.

3. Pharmacokinetic (PK): Pharmacokinetic studies provide information on what the body does to a drug. More specifically, it covers how a drug is absorbed, distributed, metabolized and eliminated by the body. Pediatric PK studies are generally performed in patients, and focus on the measurement of drug in blood, urine, or in other body fluids or tissues.

Pharmacokinetic studies are often conducted during initial drug development in order to:

- evaluate a new formulation of an existing drug;
- study how a drug may interact with other drugs;
- study what the body does to a drug in a special population of patients (for example, children and the elderly).

Pharmacokinetic information may be found in the drug labeling Clinical Pharmacology section.

4. Pharmacodynamic (PD): Pharmacodynamic studies provide information on what a drug does to the body. PD examines how a drug works in the body and the amount of drug needed to provide an effect. Pharmacodynamic information may be found in the drug labeling Clinical Pharmacology section.

5. Pharmacokinetic/Pharmacodynamic (PK/PD): A drug’s pharmacokinetic effect is usually expressed along with its pharmacodynamic effect. (The relationship between what a drug does to the body and what the body does to a drug.) PK/PD information may be found in the drug labeling Clinical Pharmacology section.

6. Tolerability: Tolerability of a drug is the degree to which drug-related side effects can be accepted by a patient. Tolerability is usually associated with the safety of a drug. Tolerability information may be found in the drug labeling Warnings & Precautions and Adverse Reactions sections.